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Specification and Drawings, as originally filed, with Application for Patent Serial No: **2,439,785,** on September 9, 2003, by **MOHAMED S.A. MAUDARBOCUS,** for "Penis Erection-Enhancing Device and Methods of Use thereof".

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PENIS ERECTION-ENHANCING DEVICE AND METHODS OF USE THEREOF

FIELD OF THE INVENTION

This invention relates to a penis erection-enhancing device and methods of treatment for males who suffer from sexual dysfunction, *e.g.*, erectile dysfunction or premature ejaculation.

BACKGROUND OF THE INVENTION

With advancing age, and also in certain pathological conditions, as well as psychological conditions, men may not be able to achieve an erection with sufficient rigidity for satisfactory sexual activity. Sexual dysfunction of men, erectile dysfunction in particular, is quite likely to become a serious problem in their sex life. For more than three decades, there has been an accelerated pace to solve the problems of erectile dysfunction. For example, clasps, splints, vacuum pumps with constriction rings, expensive surgical implants of many designs, pharmacological injections, urethral pellets, and most recently oral therapeutics containing sildenafil (*a.k.a.*, Viagra®), vardenafil (*a.k.a.*, Levitra, Nuviva), or tadalafil (*a.k.a.*, Cialis) have been developed to treat male erectile dysfunction. Side-effects, mechanical failures, injuries, serious infections, irreversible procedures, corrective surgery, and high cost, are examples of the difficulties associated with many of these approaches to restore sexual activity in males with erectile dysfunction.

Various mechanical devices can be surgically implanted in the penis to overcome erectile dysfunction. Some devices are permanently rigid and hinged. Other devices provide an inflatable chamber which becomes rigid when inflated with fluid. The inflating apparatus is also implanted within the body. These devices are not always successful. Also, these invasive procedures destroy normal tissue and suffer from surgical risks, *e.g.*, infection and hemorrhage. Moreover, there is little chance of restoring normal function when such devices are removed.

Natural therapies, *e.g.*, acupuncture, auricular therapy, ayuvedha, Unani medicine, Polarity therapy, and Bio-resonance, have also been examined for their effect on sexual function. Moreover, a full range of herbal extracts, described as male tonics, have been studied as potential therapeutics for sexual dysfunction, *e.g.*, Yohimbine, Muia Puima, Maca, Velvet antler, Ashwagandha, Tribulis Terrestris, Horny Goat weed. Many of these approaches suffer from various physical side-effects, or have had limited success in treating male erectile dysfunction.

Viagra® promotes erectile function by blocking the action of phosphodiesterase which retards the dissolution of cyclic GMP in the penis tissue. The Viagra® drug produces side-effects, however, in certain individuals suffering from heart disease or high blood pressure. The use of Viagra® may be contraindicated in subjects with neurological disorders or peripheral circulation deficiencies from diabetes mellitus, a narrowing of vessels in the lower limbs due to arteriosclerosis, other organic diseases, or those who have developed heart diseases. Furthermore, the drug should not be taken together with a hypotensor or an anti-angina drug. In addition, the drug is very expensive.

There is a continuing need in the art to provide a temporary, non-invasive device to enhance the sexual function of males, *e.g.*, erectile dysfunction and premature ejaculation, in need thereof.

SUMMARY OF THE INVENTION

The present invention provides a safe, non-invasive device most suitable for males who suffer from sexual dysfunction (*e.g.*, but not limited to, erectile dysfunction, premature ejaculation, and orgasmic problems). The device can also be used by males without erectile dysfunction, who wish to enhance their sexual function.

The penis erection-enhancing device of the present invention can be used repeatedly over an indefinite period of time. The device readily fits a user regardless of the size of the penis. The device is safe and harmless, and can be used without the need for previous medical examination and without fear of side-effects. The device needs only be worn for a few minutes to a few hours a week and it does not have to be

worn during the sexual activity. Accordingly, the device is not disturbing or intrusive to the user or his sex partner.

The device of the invention comprises a material with magnetic properties. In one embodiment, the device comprises one discrete region with magnetic properties. In another embodiment, the device comprises two regions or more regions with a magnetic composition. In yet another embodiment, the entire device is composed of a magnetic composition. The device is placed so that the sourthern pole of the magnet(s) is facing the skin of the subject.

The device of the present invention can be directly contacted with the skin of the subject or, alternatively, the device can be placed in proximity to the skin of a subject. The device is placed near, or contacted with one or more M-spots. One M-spot is located at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac, *e.g.*, if one is positioned to the side of the subject, the M-spot is located on the subject at the highest point of the scrotal sac, in the direction of the anus. Other M-spots are located in the proximal region of the penis near the pubic bone. Accordingly, in one embodiment, the device is placed near, or contacted with, one or more M-spots in the region of the proximal portion of the penis near the pubic bone. In another embodiment, the device is placed near, or contacted with the M-spot that lies at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac. In yet another embodiment, a first device is placed near, or contacted with, one or more M-spots in the region of the proximal portion of the penis near the pubic bone and a second device is placed near, or contacted with, the M-spot that lies at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic drawing illustrating cuff-shaped penis erection-enhancing devices of the present invention comprising one (panel I) or more (panel II) magnetic regions.

DETAILED DESCRIPTION OF THE INVENTION

I. The Penis Erection-enhancing Device

The device of the invention comprises a material with magnetic properties that is placed in proximity to the skin of a subject in need of enhanced sexual function such that the sourthern pole of the magnet(s) is facing the skin of the subject.

In one embodiment, the device comprises one discrete region with magnetic properties. In another embodiment, the device comprises two or more regions with a magnetic composition (*see, e.g.*, Figure 1). In yet another embodiment, the entire device is composed of a magnetic composition.

In one embodiment, the device comprises at least one magnetic region with a potential magnetic flux density of at least about 500-15,000 gauss. In another embodiment, the device comprises at least one magnetic region with a potential magnetic flux density of at least about 5,000-15,000 gauss. In yet another embodiment, the device comprises at least one magnetic region with a potential magnetic flux density of at least about 5,000-9,000 gauss. In still another embodiment, the device comprises as least one magnetic region with a potential magnetic flux density of at least about 9,000 gauss.

The device can be directly contacted with the skin of the subject or, alternatively, the device can be placed in proximity to the skin of a subject. The inventor identified areas on the skin, termed "M-spots," with a role in erectile function by measuring the electrical resistance of points on the penis surface and scrotal area and charting an electrical map of the penis and scotal area so as to identify the control points of the male organ tonus. For example, one M-spot is located at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac. Other M-spots are located in the proximal region of the penis near the pubic bone. Specifically, M-spots in this region include, but are not limited to, positions on the dorsal aspect (12 o'clock position), the ventral aspect (6 o'clock position), as well as both sides (3 o'clock position and 9 o'clock position, respectively) of the proximal region of the penis near the pubic bone. Accordingly, in one embodiment, the device of the present

invention is placed near, or contacted with, the region of the proximal portion of the penis near the pubic bone. In another embodiment, the device of the present invention is placed near, or contacted with one or more M-spots in the region of the proximal portion of the penis near the pubic bone where the surface electrical resistance is lower than the surface electrical resistance in neighboring regions of the penis. In yet another embodiment, the device of the present invention is placed near, or contacted with, the M-spot that lies at the posterior part of the scrotal sac, at the junction between the perineum and the start of the scrotal sac where surface electrical resistance is lower than the surface electrical resistance in neighboring areas of this region.

The device of the present invention can be any suitable shape, *e.g.*, disc, square, triangle, rectangle, circle, oval, trapazoid, rod, or cuff. The device can be comprised of any suitable material, or combination of materials, *e.g.*, but not limited to, metal, ceramic, glass, plastic, rubber, latex, and textile, *e.g.*, silk and wool.

The device of the present invention comprises magnetic materials that are conventional magnets with one pole on each side of the magnet, *i.e.*, North pole on one side, South pole on the other side of the magnet. The magnetic region(s) of the device may be comprised of permanent or temporary magnets. Permanent magnets suitable for use in the present invention, include, but are not limited to, *e.g.*, ceramic, alnico, samarium cobalt, neodymium iron boron, injection-molded and flexible.

Ceramic, also known as Ferrite, magnets are made of a composite of iron oxide and barium/strontium carbonate. These materials are readily available and at a lower cost than other types of materials used in permanent magnets making it desirable due to the lower cost. These magnets are also made in different grades. Ceramic-1 is an isotropic grade with equal magnetic properties in all directions. Ceramic grades 5 and 8 are anisotropic grades. Anistropic magnets are magnetized in the direction of pressing. The anisotropic method delivers the highest energy product among ceramic magnets at values up to 3.5 MGOe (Mega Gauss Oersted). Ceramic magnets have a good balance of magnetic strength, resistance to demagnetizing and economy.

Alnico magnets are made up of a composite of aluminum, nickel and cobalt with small amounts of other elements added to enhance the properties of the magnet.

Alnico magnets have good temperature stability, good resistance to demagnetization due to shock but they are easily demagnetized. Sintering offers superior mechanical characteristics, whereas casting delivers higher energy products (up to 5.5 MGOe) and allows for the design of intricate shapes. Two very common grades of Alnico magnets are 5 and 8. These are anisotropic grades and provide for a preferred direction of magnetic orientation. Alnico magnets have been replaced in many applications by ceramic and rare earth magnets.

Samarium cobalt is a type of rare earth magnet materials that are highly resistant to oxidation, have a higher magnetic strength and temperature resistance than Alnico or Ceramic materials. Introduced to the market in the 1970's, samarium cobalt magnets continue to be used today.

Neodymium Iron Boron (NdFeB) material is another type of rare earth magnetic materials. This material has similar properties as the Sumarium Cobalt except that it is more easily oxidized and generally doesn't have the same temperature resistance. NdFeB magnets also have the highest energy products approaching 50MGOe. Their high energy products lend themselves to compact designs that result in innovative applications and lower manufacturing costs. NdFeB magnets are highly corrosive. Surface treatments have been developed that allow them to be used in most applications. These treatments include gold, nickel, zinc and tin plating and epoxy resin coating.

Injection-moldable magnets are a composite of resin and magnetic powders of different materials allowing parts to be made in an injection molding process. Energy products are dependent upon the magnetic powders used in fabrication. The molding process allows for the manufacture of more complex shapes. These magnets are usually lower in magnetic strength as there are limitations to the degree of loading.

Flexible magnets are very similar to the injection molded magnets but are produced in flat strips and sheets. These magnets are lower in magnetic strength and very flexible depending on the materials that were used in the compound with the magnetic powders. Vinyl is often used in this type of magnet as the binder.

The device may be held in the area of one or more M-spots by any suitable means. Likewise, the device can be temporarily affixed to one or more M-spots by any suitable means, *e.g.*, bandage, elastic band, or adhesive. The device can be removed for later reuse. The device may be removed prior to sexual activity or the device may be worn during sexual activity.

The magnetic region(s) of the device may be any shape or dimension suitable to yield the desired magnetic flux density. In one embodiment, the magnetic region(s) of the device is dot-shaped. Further, the magnetic region(s) of the device may be comprised of a plurality of subregions with the same or differing shape, dimension, or magnetic strength, *i.e.*, magnetic flux density potential, dimension, suitable to yield the desired magnetic flux density. In one embodiment, the magnetic region(s) of the device has a diameter of at least about 0.1-1.0 cm and a height of at least about 0.1-1.0 cm. In one embodiment, the magnetic region(s) of the device has a diameter of at least about 0.1-0.5 cm and a height of at least about 0.1-0.5 cm. In yet another embodiment, the magnetic region(s) of the device has a diameter of at least about 0.1 cm and a height of at least about 0.1 cm. In yet another embodiment, the device of the invention comprises a dot-shaped magnetic region of about 0.5 cm diameter and about 0.3 cm height.

In one embodiment, the device comprises a material with magnetic properties in the shape of a cuff which encircles the shaft of the penis at its proximal portion near the pubic bone. In an alternate embodiment, the cuff has a gap which allows for appropriate adjustment of the device to the girth of the penis as well as to accommodate expansion of the device and to prevent penis tissue injury (see Figure 1).

In one embodiment, the cuff has one (see Figure 1, panel I) discrete magnetic region. In another embodiment, the cuff has two or more discrete magnetic regions (see Figure 1, panel II). The discrete magnetic regions may have the same or differing magnetic flux density potential. The regions may be placed in a variety of orientations so long as the southern pole of one magnetic region is oriented toward the skin in the area of the proximal portion of the penis near the pubic bone, *e.g.*, region with one or

more M-spots. The cuff has a length, extending distally toward the penile glans a distance preferably of 1 to 50 millimeters.

II. Treating Male Erectile Dysfunction Using the Penis Erection-Enhancing Device

The invention provides a method of treating a subject in need of enhanced sexual function the method comprising exposing one M-spot, or more than one M-spot, *e.g.*, two, three, four, or more M-spots, of a mammalian subject in need of treatment to the southern pole of one or more magnetic regions of the device of the present invention for up to 5 hours prior to sexual activity, *e.g.*, sexual intercourse. Exposure of one M-spot, or more than one M-spot, *e.g.*, two, three, four, or more M-spots, to the southern pole of one or more magnetic regions of the device of the present invention may be performed once daily or more than once each day, or a few times a week, for a period of days, or for a period of weeks, or for a period of months until the subject experiences improved erectile function relative to the erectile function of the subject prior to use of the device of the present invention. The subject may be any mammal, *e.g.*, bull, horse, rabbit, pig, dog, or cat, in need of enhanced sexual function. In a preferred embodiment the mammalian subject is a human subject.

Generally, the device is used for as long as it is comfortable to the subject. When the subject feels tingling or "a sensation of fullness" in the zone of application, the device can be removed. In a preferred embodiment, the device is applied for about 3 hours or less.

Ordinarily, the user need not be sexually aroused by massage, foreplay, or by use of a vacuum chamber before applying the device for successful operation. The user of the device of the invention can experience enhanced sexual function as manifested by effects and advantages such as, *e.g.*, improved early morning erection, increased erectile frequency, increased penile strength, decreased post-ejaculatory recovery time, increased intercourse frequency, increased scrotal tone, *i.e.*, tension in the scrotal tissue that brings the testicles closer to the body, or increased penile length and girth.

Though typical preferred embodiments, the effects and advantages of the present invention are not limited to them. It should be construed that the present invention may be practiced in different manners by changing the application methods within the range of the effects described later in order to fulfill the purposes mentioned above.

The present invention, compared with the drug Viagra® does not require prior medical consultation before use and is not contraindicated for diabetics, hypertensive subjects and patients suffering from angina. In addition, it does not have to be purchased at high cost after each time of use. It does not cause fear among users of side-effects or excessive medical effect by overdose, either. It does not burden the heart or other organs. It can be used while maintaining the natural physical state of the user without causing any adverse side-effects.

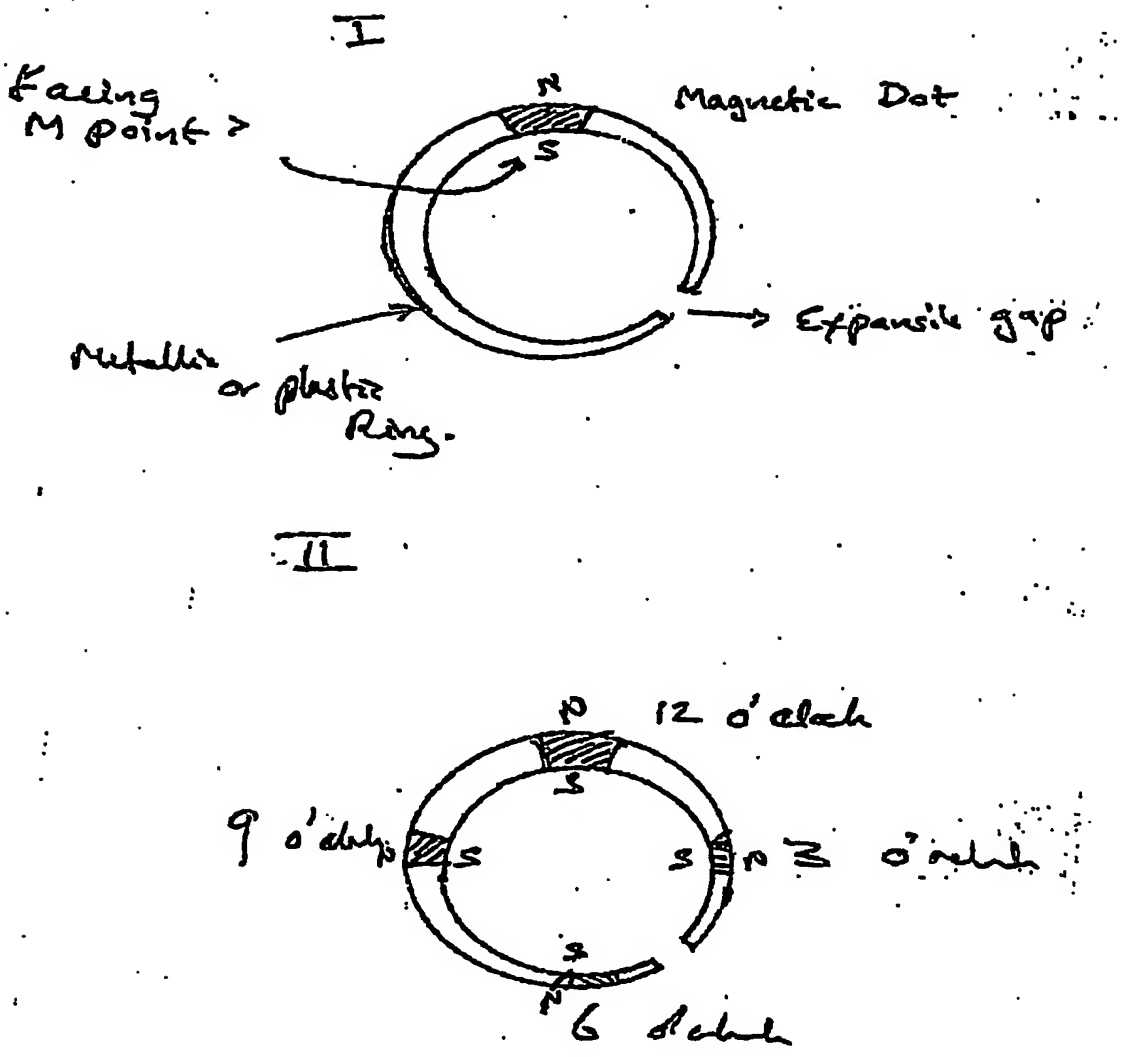
The following observations have been made in human trials where the subject applied a device of the present invention as a cuff around the base of the penis for up to three hours per day.

Day 1	A little tingling or warm sensation will often be felt.
Day 2, 3	Stronger morning erections, slight increase in penile girth and temperature very often noted even at this early stage.
Day 4, 5, 6, 7	Stronger erections, more control during intercourse, and shorter recover time post ejaculation.

After 2 weeks of daily use, almost 90% of users feel fully energized in their male functions and at this point a maintenance regime can be started.

Each week, 2 sessions of 30 mins up to 3 hours can be maintained depending on physical condition of the person and his sexual activity frequency.

Figure 1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